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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

**[Docket No. DEA-413]**

**Schedules of Controlled Substances: Temporary Placement of Acetyl Fentanyl into Schedule I**

**AGENCY:** Drug Enforcement Administration, Department of Justice

**ACTION:** Notice of intent.

**SUMMARY:** The Administrator of the Drug Enforcement Administration is issuing this notice of intent to temporarily schedule the synthetic opioid, *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (acetyl fentanyl), into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of this opioid substance into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to schedule I substances under the Controlled Substances Act on the manufacture, distribution, possession, importation, exportation, research, and conduct of instructional activities of this opioid substance.

**DATES:** [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:** Any final order will be published in the Federal Register and may not be effective prior to [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

### **Legal Authority**

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801-971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21

U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308. 21 U.S.C. 812(a).

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he or she finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

## **Background**

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of her intention to temporarily place a substance into schedule I of the CSA.<sup>1</sup> The

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<sup>1</sup> Because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this notice of intent, all subsequent references to “Secretary” have been replaced with “Assistant Secretary.” As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as

Administrator transmitted notice of her intent to place acetyl fentanyl in schedule I on a temporary basis to the Assistant Secretary by letter dated April 7, 2015. Any comments submitted by the Assistant Secretary in response to the notice transmitted to the Assistant Secretary shall be taken into consideration before a final order is published. 21 U.S.C. 811(h)(4).

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): the substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

### **Acetyl Fentanyl**

Available data and information for acetyl fentanyl indicate that this opioid substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

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the lead agency within HHS in carrying out the Assistant Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

#### **Factor 4. History and Current Pattern of Abuse**

Clandestinely produced substances structurally related to the schedule II opioid analgesic fentanyl were trafficked and abused on the West Coast in the late 1970s and 1980s. These clandestinely produced fentanyl-like substances were commonly known as designer drugs and recently, there has been a reemergence in the trafficking and abuse of designer drug substances including fentanyl-like substances. Alpha-methylfentanyl, the first fentanyl analogue identified in California, was placed into schedule I of the CSA in September 1981. Following the control of alpha-methylfentanyl, the DEA identified several other fentanyl analogues (3-methylthiofentanyl, acetyl-alpha-methylfentanyl, beta-hydroxy-3-methylfentanyl, alpha-methylthiofentanyl, thiofentanyl, beta-hydroxyfentanyl, para-fluorofentanyl and 3-methylfentanyl) in submissions to forensic laboratories. These substances were temporarily controlled under schedule I of the CSA after finding that they posed an imminent hazard to public safety and were subsequently permanently placed in schedule I of the CSA.

The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories across the country. The first laboratory submission of acetyl fentanyl was recorded in Maine in April 2013 according to NFLIS. NFLIS registered eight reports containing acetyl fentanyl in 2013 in Louisiana, Maine, and North Dakota; and 30 reports in 2014 in Florida, Illinois, Louisiana, Maine, New Jersey, Ohio, Oregon, Pennsylvania, and Virginia.

The System to Retrieve Information from Drug Evidence (STRIDE) is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other Federal agencies, and some local law enforcement agencies. Acetyl fentanyl was first reported to STRIDE in September 2013 from exhibits obtained through a controlled purchase in Louisiana. In October 2013, an exhibit collected from a controlled purchase of suspected oxycodone tablets in Rhode Island contained acetyl fentanyl as the primary substance. In 2014, STARLiMS (a web-based, commercial laboratory information management system that is in transition to replace STRIDE) and STRIDE reported eight additional seizures in Colorado, Florida, Georgia, and Washington.

In August 2013, the Centers for Disease Control and Prevention (CDC) published an article in its Morbidity and Mortality Weekly Report documenting a series of 14 fatalities related to acetyl fentanyl that occurred between March and May 2013. In December 2013, another fatality associated with acetyl fentanyl was reported in Rhode Island for a total of 15 fatalities. In February 2014, the North Carolina Department of Health and Human Services issued a health advisory related to acetyl fentanyl following at least three deaths related to this synthetic drug. Toxicologists at the North Carolina Office of the Chief Medical Examiner detected acetyl fentanyl in specimens associated with deaths that occurred in January 2014 in Sampson, Person, and Transylvania counties. In July and August 2014, four additional fatalities involving acetyl fentanyl were reported for a total of seven fatalities in North Carolina. Deaths involving acetyl fentanyl have also been reported in California (1), Louisiana (14), Oregon (1), and Pennsylvania (1).

A significant seizure of acetyl fentanyl occurred in April 2013 during a law enforcement investigation in Montreal, Canada. Approximately three kilograms of acetyl fentanyl in powder form and approximately 11,000 tablets containing acetyl fentanyl were seized. Given that a typical dose of acetyl fentanyl is in the microgram range, a three kilogram quantity could potentially produce millions of dosage units. In the United States, tablets that mimic pharmaceutical opioid products have been reported in multiple states, including Colorado, Florida, Georgia, Rhode Island, and Washington. Recent reports indicate that acetyl fentanyl in powder form is available over the Internet and has been imported to addresses within the United States.

Evidence also suggests that the pattern of abuse of fentanyl analogues, including acetyl fentanyl, parallels that of heroin and prescription opioid analgesics. Seizures of acetyl fentanyl have been encountered both in powder and in tablet form. It is also known to have caused many fatal overdoses, in which intravenous routes of administration and histories of drug abuse are documented.

#### **Factor 5. Scope, Duration and Significance of Abuse**

DEA is currently aware of at least 39 fatalities associated with acetyl fentanyl. These deaths have been reported in 2013 and 2014 from six states including California, Louisiana, North Carolina, Oregon, Pennsylvania, and Rhode Island. STARLiMS and STRIDE, databases capturing drug evidence information from DEA forensic laboratories, have a total of 10 drug reports in which acetyl fentanyl was identified in six cases for analyzed drugs submitted from January 2010 – December 2014 from Colorado, Florida, Georgia, Louisiana, Rhode Island, and Washington. It is likely that the prevalence of acetyl fentanyl in opioid analgesic-related emergency room admissions and deaths is

underreported as standard immunoassays cannot differentiate acetyl fentanyl from fentanyl.

The population likely to abuse acetyl fentanyl overlaps with the populations abusing prescription opioid analgesics and heroin. This is evidenced by the routes of administration and drug use history documented in acetyl fentanyl fatal overdose cases. Because abusers of acetyl fentanyl are likely to obtain the drug through illicit sources, the identity, purity, and quantity is uncertain and inconsistent, thus posing significant adverse health risks to its abusers. This risk is particularly heightened by the fact that acetyl fentanyl is a highly potent opioid (15.7-fold more than that of morphine as tested in mice using an acetic acid writhing method). Thus small changes in the amount and purity of the substance could potentially lead to overdose and death.

#### **Factor 6. What, if Any, Risk There Is to the Public Health**

Acetyl fentanyl exhibits a pharmacological profile similar to that of fentanyl and other opioid analgesic compounds and it is a potent opioid analgesic reported to be 1/3 as potent as fentanyl and 15.7 times as potent as morphine in mice tested in an acetic acid writhing method. In addition, studies also showed that the range between the effective dose (ED50) and the lethal dose (LD50) of acetyl fentanyl is narrower than that of morphine and fentanyl, increasing the risk of fatal overdose. Thus, its abuse is likely to pose quantitatively greater risks to the public health and safety than abuse of traditional opioid analgesics such as morphine.

Based on the above pharmacological data, the abuse of acetyl fentanyl at least leads to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic compounds. The public health risks attendant to the abuse of heroin and opioid analgesics

are well established. The abuse of opioid analgesics has resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

Acetyl fentanyl has been associated with numerous fatalities. At least 39 overdose deaths due to acetyl fentanyl abuse have been reported in six states in 2013 and 2014, including California, Louisiana, North Carolina, Oregon, Pennsylvania, and Rhode Island. This indicates that acetyl fentanyl poses an imminent hazard to public safety.

### **Finding of Necessity of Schedule I Placement to Avoid Imminent Hazard to Public Safety**

Based on the above summarized data and information, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of acetyl fentanyl pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for this substance in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for acetyl fentanyl indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated April 7, 2015, notified the Assistant Secretary of the DEA's intention to temporarily place this substance in schedule I.

### **Conclusion**

This notice of intent initiates an expedited temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein set forth the grounds for her determination that it is necessary to temporarily schedule acetyl fentanyl in schedule I of the CSA, and finds that placement of this opioid substance into schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds that it is necessary to temporarily place this synthetic opioid into schedule I to avoid an imminent hazard to the public safety, any subsequent final order temporarily scheduling these substances will be effective on the date of publication in the Federal Register, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Administrator to issue such a final order as soon as possible after the expiration of 30 days from the date of publication of this notice. Acetyl fentanyl will then be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, possession, importation, exportation, research, and conduct of instructional activities of a schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done “on the record after opportunity for a hearing” conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government

with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

### **Regulatory Matters**

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the *Federal Register* of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator will take into consideration any comments submitted by the Assistant Secretary with regard to the proposed temporary scheduling order.

Further, the DEA believes that this temporary scheduling action is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### **List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA proposes to amend 21 CFR Part 1308 as follows:

**PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES**

1. The authority citation for part 1308 continues to read as follows:

**Authority:** 21 U.S.C. §§ 811, 812, 871(b), unless otherwise noted.

2. In § 1308.11, add paragraph (h)(24) to read as follows:

**§ 1308.11 Schedule I**

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(h) \* \* \*

(24) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: acetyl fentanyl).....(9821)

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Dated: May 14, 2015

Michele M. Leonhart,  
*Administrator*

